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Pfizer Shares Safety Data on Azithromycin-Hydroxychloroquine Combination

Company Follows Up on Recently Made Commitment as Part of Five-Point Plan

NEW YORK, March 25, 2020—Pfizer Inc. (NYSE: PFE) today followed up on the recently made commitment to share data and knowledge as part of our five-point plan to battle the COVID-19 pandemic. The company is sharing information that could benefit the many companies and organizations who are working quickly to provide solutions to combat this unprecedented healthcare crisis.

Recently, a group of French researchers disclosed results of an independent study in France exploring the use of hydroxychloroquine in 20 patients for the potential treatment of COVID-19 disease[i]. Among those 20 patients, six also received Pfizer's product, azithromycin (Zithromax®). In that study, the proportion of patients with virologic cure after 6 days (as indicated by negative PCR tests) was higher in the 20 patients who received hydroxychloroquine as compared to the 16 controls. The highest rate of cure was seen in those that also received azithromycin—all six of those patients achieved virologic cure. In light of these preliminary findings, and as Pfizer interprets the data in the context of previous research into other infectious diseases, the company would like to share additional information that may facilitate the further exploration of this combination.

Pfizer has extensive expertise on azithromycin and has studied the anti-infective across many infectious diseases both alone and in combination with other therapies, including chloroquine. While Pfizer has not studied the azithromycin-hydroxychloroquine combination in treatment of

COVID-19 disease, the company did explore the use of a fixed-dose combination of azithromycin and chloroquine in treatment[ii] and prevention[iii] trials for malaria in Africa. In the treatment trial, the primary efficacy endpoints were met, and the authors concluded that azithromycin-chloroquine was non-inferior to treatment with mefloquine and was well tolerated. In addition, a study for preventative treatment of malaria infection in pregnant women did not meet its prespecified efficacy endpoints, however the combination of azithromycin 1,000 mg and chloroquine 620 mg per day for 3 days had an acceptable safety profile based from data collected in 1,446 pregnant women in sub-Saharan Africa.

In addition, both female and male elderly patients with significant co-morbidities were studied in large randomized trials for the prevention of cardiovascular events in the WIZARD[iv] and ACES[v] studies, and while the primary endpoint did not meet pre-specified efficacy, the safety profile was consistent with previous smaller studies published for approved indications in a population with a similar age profile and co-morbidities to the COVID-19 disease population reportedly most at risk for severe outcomes.

It is important to note that the doses Pfizer has studied with the combination of azithromycin and chloroquine in malaria may have a different safety profile than the recently reported study combining azithromycin with hydroxychloroquine. Pfizer would like to highlight these published studies to facilitate further research efforts to study azithromycin in combination with other agents to mitigate COVID-19 disease. The company has committed resources for a technical team to complete an analysis of relevant data within Pfizer and published in peer reviewed literature and will plan to share this information as we explore the next steps for Pfizer and our partners in further evaluating combination therapies with azithromycin.

About Pfizer: Breakthroughs That Change Patients' Lives

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.Pfizer.com. In addition, to learn more, please visit us on www.Pfizer.com and follow us on Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

Disclosure Notice

The information contained in this press statement is as of March 24, 2020. Pfizer assumes no obligation to update forward-looking statements contained in this press statement as the result of new information or future events or developments.

This release contains forward-looking information about Pfizer's efforts to battle COVID-19 and potential combination therapies involving azithromycin and its potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including uncertainties regarding the results of screening and the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable pre-clinical or clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from clinical studies; whether and when drug applications for any potential antiviral compounds or combination therapies may be filed or approved in any jurisdictions, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of any such products; manufacturing capabilities; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2019 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

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[i] Gautret et al. (2020) Hydroxychloroquine and azithromycin as a treatment of COVID-19: results of an open-label non-randomized clinical trial. International Journal of Antimicrobial Agents – In Press 17 March 2020 – DOI : 10.1016/j.ijantimicag.2020.105949

[ii] Sagara I, Oduro AR, Mulenga M, et al. Efficacy and safety of a combination of azithromycin and chloroquine for the treatment of uncomplicated Plasmodium falciparum malaria in two multi-country randomised clinical trials in African adults. *Malar J*. 2014;13:458. Published 2014 Nov 25. doi:10.1186/1475-2875-13-458

[iii] Kimani J, Phiri K, Kamiza S, Duparc S, Ayoub A, Rojo R, et al. (2016) Efficacy and Safety of Azithromycin-Chloroquine versus Sulfadoxine-Pyrimethamine for Intermittent Preventive Treatment of Plasmodium falciparum Malaria Infection in Pregnant Women in Africa: An Open-Label, Randomized Trial. PLoS ONE 11(6): e0157045. doi:10.1371/journal.pone.0157045

[iv] O'Connor CM, Dunne MW, Pfeffer MA, Muhlestein JB, Yao L, Gupta S, Benner RJ, Fisher MR, Cook TD; Investigators in the WIZARD Study. Azithromycin for the secondary prevention of coronary heart disease events: the WIZARD study: a randomized controlled trial. JAMA. 2003 Sep 17;290(11):1459-66.

[v] Grayston JT, Kronmal RA, Jackson LA, Parisi AF, Muhlestein JB, Cohen JD, Rogers WJ, Crouse JR, Borrowdale SL, Schron E, Knirsch C; ACES Investigators. Azithromycin for the secondary prevention of coronary events. N Engl J Med. 2005;352:1637-45.